

EPA Reg. No. 2596-179
Vol. 2



March 15, 2016

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is submitting this notice under provision of our Conditional Registration to supply a projected "release for shipment date" for the following products:

- Hartz Reference 143, EPA Reg. No. 2596-178 and;
- Hartz Reference 144, EPA Reg. No. 2596-179.

The shipment dates for both are projected for March 18, 2016.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 7562 or email me at lhemsarh@hartz.com.

Sincerely,

A handwritten signature in black ink that reads "Lance Hemsarh". Below the signature, the date "3.15.16" is written and circled.

Lance Hemsarh
Senior Director, Research and Development

PROCESSING REQUEST

Reg # 2396-179

Decision # 513131

Description: MINOR EDITING to label

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☒ Dated: 2-6-16

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 2.9.16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 6, 2016

W. Lance H. Hemsarh
Senior Director R&D
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Notification per PRN 98-10 – Multiple Minor Revisions
Product Name: Hartz Reference #144
EPA Registration Number: 2596-179
Application Date: 1/12/2016
Decision Number: 513131

Dear Mr. Hemsarh:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", is written over a horizontal line.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

January 12, 2016

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	78.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

NOTIFICATION

2596-179

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/06/2016

January 12, 2016

[For 1 applicator pack]

(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, Weighing 3 lbs. or more.	0.017 FL. OZ. (0.5 ML) (Applicator)
--	-------------------------------------

[For 3 applicator pack]

(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, Weighing 3 lbs. or more.	0.051 FL. OZ. (1.5 ML), Contains 3 (-) (tubes, each) 0.017fl. oz. (0.5ml) (Applicators)
--	---

[For 6 applicator pack]

(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, Weighing 3 lbs. or more.	0.102 FL. OZ. (3.0 ML), Contains 6 (-) (tubes, each) 0.017fl. oz. (0.5ml) (Applicators)
--	---

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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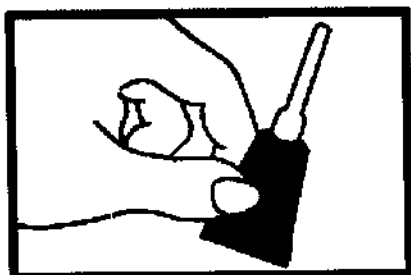
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

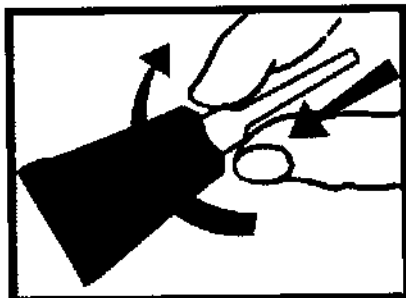
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS**

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin

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level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar[®]). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

(With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.)

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

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PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-179
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.80%, (S)-Methoprene 11.80%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-179

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

(Product Name) contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). (Product Name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) that live in your home

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) to prevent the eggs from hatching in your home

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

Kills fleas, (kills) flea eggs, (kills) flea larvae and (kills) ticks (including those that may transmit Lyme disease)

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, (Kills)Ticks, (Kills)Flea eggs, ((Kills)Flea larvae), (Kills)Chewing Lice
Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.
Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Stays on and doesn't rub off
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Dual insect growth regulator (IGR) prevents re-infestation
Contains two ingredients to prevent flea infestations
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Effective after bathing
Effective after exposure to water
Patents Pending
Easy spot on topical applicator
Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.
(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)
(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)
Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more
Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose

First month, second month, third month, fourth month, fifth month, sixth month

Value pack

1 month supply

3 month supply

6 month supply

1 (monthly) treatment

3 (monthly) treatment(s)

6 (monthly) treatment(s)

1 (monthly) dose

3 (monthly) doses

6 (monthly) doses

Apply (monthly) (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to (your cat's) skin

(Easy) (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear (wet) (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

(Single Dose Pack) (Single Unit Pack) (Individual Unit) (Not For Sale)

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First (Dose)(Application) _____

Second (Dose)(Application) _____

Third (Dose)(Application) _____

Fourth (Dose)(Application) _____

Fifth (Dose)(Application) _____

Sixth (Dose)(Application) _____

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase (Brand name).

After treating your pet for the first time, peel off the sticker and place on your calendar that day. Place the remaining stickers on your calendar as a reminder to apply (Brand name) monthly.

Calendar Reminder Stickers

Don't forget to re-purchase
6 months use all 6 stickers
3 months (use all 3 stickers)
[Individual stickers] Apply (Brand name)
[Individual sticker] Re-purchase (Brand name)

Use these calendar stickers as a reminder for when to reapply

(Apply) (First) (1st) Month (Brand Name)
(Reapply) (Second) (2nd) Month (Brand Name)
(Reapply) (Third) (3rd) Month (Brand Name)
(Reapply) (Fourth) (4th) Month (Brand Name)
(Reapply) (Fifth) (5th) Month (Brand Name)
(Reapply) (Sixth) (6th) Month (Brand Name)

Questions? Contact your veterinarian or call our technical experts at 1-800-275-1414, (twenty four) (24) hours per day, (seven) (7) days per week.
Consult veterinarian before use



Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)
Nylar® - Registered Trademark of McLaughlin Gormley King Company
EPA Reg. No. 2596-179
EPA Est. No. 2596-OH-I



January 12, 2016

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis PM-3

"Notification to add optional marketing statements per PR Notice 98-10" for Hartz Ref 144, EPA Reg. No. 2596-179.

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this Notification to add optional marketing statements per PR Notice 98-10.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Included with this application are:

- Completed application form 8570-1;
- 3 copies of the Master Label. Additions are highlighted.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 2269 email me at lhemsarth@hartz.com

Sincerely,

A handwritten signature in black ink, appearing to read "W. Lance H. Hemsarth".

W. Lance H. Hemsarth
Senior Director, Research & Development

Encl.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-179	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #144	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTL. MRIDs from data filed with that action cited herein.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. Varies	No. per container see label	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see label		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product Printed		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other on doses			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name W. Lance H. Hemsarh		Title Senior Director R&D	
		Telephone No. (Include Area Code) 201-271-4800, ext 2269	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Director R&D	
4. Typed Name W. Lance H. Hemsarh		5. Date 1-12-16	

PROCESSING REQUEST

Reg # 2596-179

Decision # 510975

Description: Revised Bior CSF

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 11-3-2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 1-13-2016

PROCESSING REQUEST

Reg # 2596-179 Decision # 511935

Description: additional marketing & Net Content
language

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☒ Dated: 12-31-2015

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Angela Hollis

Division: RD

Phone: 347-0216

Date: 1-5-2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 20, 2016

Anna McGrath
Regulatory Affairs Specialist
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094

Subject: CSF Notification per PRN 98-10 – Revised Basic CSF
Product Name: Hartz Reference #144
EPA Registration Number: 2596-179
Application Date: November 3, 2015
Decision Number: 510975

Dear Ms. McGrath:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSF submitted with your application has been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated November 3, 2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-179	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #: 144	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, New Jersey 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION

JAN 20 2016

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification for a Minor Formulation Amendment to add additional source of inert ingredient per PR Notice 98-10."

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/>
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Anna McGrath	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 201-271-4800 ext. 7015
----------------------	--	---

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Anna McGrath	5. Date November 3, 2015	

20



November 3, 2015

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis, PM-3

"Notification for a Minor Formulation Amendment to add additional source(s) of approved inert ingredient(s) per PR Notice 98-10" for Hartz Ref # 144 EPA Reg. No. 2596-179.

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this Notification for a Minor Formulation Amendment to add additional source(s) of an approved inert ingredient(s) per PR Notice 98-10.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Included with this application are:

- Completed application form 8570-1;
- Two copies of new Basic Confidential Statement of Formula, dated 11/3/15
- ~~Two~~ copies of new Alternate Confidential Statement of Formula #1, dated 11/3/15 *was not submitted 5/11/15*
- Copies of prior approved Basic Confidential Statement of Formula and Alternate Confidential Statement of Formula, dated 3/11/14. *Ditto*

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 7015 or email me at amcgrath@hartz.com

Sincerely,

Anna McGrath
Regulatory Affairs Specialist



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094	EPA File Symbol/Registration Number 2596-179
	Product Name Hartz Reference #144
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/03/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile; (S)-Methoprene and; Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitril	[REDACTED]	[REDACTED]
(S)-Methoprene	[REDACTED]	[REDACTED]
Pyriproxyfen	[REDACTED]	[REDACTED]
Signature 	Name and Title Lance Hemsarh, Sr. Director, R&D	Date 01/20/2016

EPA Form 8570-27 (Rev. 08-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 31, 2015

Lance Hemsarth
Senior Director
Research & Development
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Notification per PRN 98-10 – Additional Marketing Statements & Net Contents
Product Name: Hartz Reference #144
EPA Registration Number: 2596-179
Application Date: 12/4/2015
Decision Number: 511935

Dear Mr. Hemsarth:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis".

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Hartz® Reference # 144

Alternate Brand Names

Hartz® Pro Force Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ for Cats (& Kittens)
Hartz® FieldForce Pro™ for Cats (& Kittens)
Hartz® First Defense Pro™ for Cats (& Kittens)

Hartz® Pro Force™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
Hartz® First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FieldForce Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Treatment for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Treatment for Cats (& Kittens)

FieldForce Pro™ for Cats (& Kittens)
First Defense Pro™ for Cats (& Kittens)
FieldForce Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Action Topical Solution for Cats (& Kittens)
First Defense Pro™ Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
Pyriproxyfen.....	0.25%
OTHER INGREDIENTS	78.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

NOTIFICATION

2596-179

The applicant has certified that no changes, other than those reported to the Agency, have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/31/2015

December 30, 2015

[For 1 applicator pack]

(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, weighing 3 lbs. or more.	0.017 FL. OZ. (0.5 ML) (Applicator)
---	--

[For 3 applicator pack]

(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, weighing 3 lbs. or more.	0.051 FL. OZ. (1.5 ML), Contains 3 (-) (tubes, each) 0.017fl. oz. (0.5ml) (Applicators)
---	--

[For 6 applicator pack]

(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, weighing 3 lbs. or more.	0.102 FL. OZ. (3.0 ML), Contains 6 (-) (tubes, each) 0.017fl. oz. (0.5ml) (Applicators)
---	--

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414, twenty-four (24) hours per day, seven (7) days per week.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

December 30, 2015

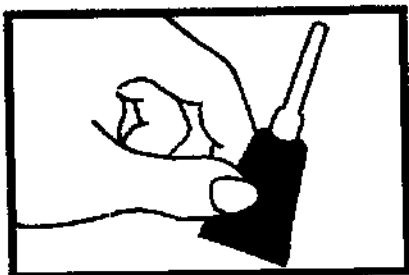
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

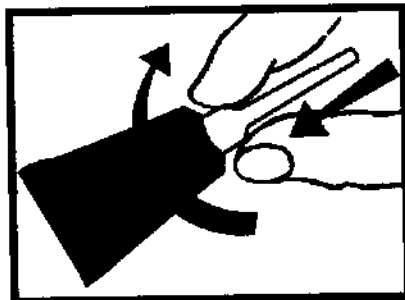
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS**

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens 8 weeks or older as follows:



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin

level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

4. Repeat once a month.

SIDE EFFECTS

Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

(With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.)

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 2596-179
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

INDIVIDUAL TUBE TEXT

(Product Name)

Only for use on cats 8 weeks and older weighing 3 lbs or more

0.017 fl oz (0.5ml)

Contains Fipronil 9.80%, (S)-Methoprene 11.80%, Pyriproxyfen (Nylar®) 0.25%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2596-179

EPA Est. No. 2596-OH-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult fleas, flea eggs, and flea larvae

Prevents all flea stages (eggs, larvae, pupae) from developing

Kills fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Prevents Flea Eggs from hatching

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) that live in your home

Kills flea eggs on your (cat *or* kitten *or* cat and kitten) to prevent the eggs from hatching in your home

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, (Flea larvae), Chewing Lice

Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks)

December 30, 2015

Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.
Kills Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)
Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Dual insect growth regulator (IGR) prevents re-infestation

Contains two ingredients to prevent flea infestations

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Patents Pending

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

(Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs)

Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more

Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose

First month, second month, third month, fourth month, fifth month, sixth month

Value pack

1 month supply

3 month supply

6 month supply

1 monthly treatment

3 monthly treatment(s)

6 monthly treatment(s)

1 monthly dose

3 monthly doses

6 monthly doses

Apply monthly (every 30 days)

Convenient (easy to use) applicator

(3) Pro-cision Flo® Applicator(s) (included)

With Pro-cision Flo® Applicator

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

Easy (simple) to use (handle) (apply)

Made in the U.S.A

Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

(Single Dose Pack) (Single Unit Pack) (Individual Unit) (Not For Sale)

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose	_____
Second Dose	_____
Third Dose	_____
Fourth Dose	_____
Fifth Dose	_____
Sixth Dose	_____

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase (Brand name).

After treating your pet for the first time, peel off the sticker and place on your calendar that day. Place the remaining stickers on your calendar as a reminder to apply (Brand name) monthly.

Calendar Reminder Stickers

Don't forget to re-purchase

6 months use all 6 stickers

3 months

December 30, 2015

[Individual stickers] Apply (Brand name)
[Individual sticker] Re-purchase (Brand name)

Use these calendar stickers as a reminder for when to reapply

(Apply) (First) (1st) Month (Brand Name)
(Reapply) (Second) (2nd) Month (Brand Name)
(Reapply) (Third) (3rd) Month (Brand Name)
(Reapply) (Fourth) (4th) Month (Brand Name)
(Reapply) (Fifth) (5th) Month (Brand Name)
(Reapply) (Sixth) (6th) Month (Brand Name)

Questions? Contact your veterinarian or call our technical experts at 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week.

Consult veterinarian before use



Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)
Nylar® - Registered Trademark of McLaughlin Gormley King Company
EPA Reg. No. 2596-179
EPA Est. No. 2596-OH-1



December 4, 2015

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis PM-3

"Notification to add optional marketing statements per PR Notice 98-10" for Hartz Ref 143, EPA Reg. No. 2596-179.

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this Notification to add optional marketing statements per PR Notice 98-10.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Label additions have been highlighted, including the following changes noted below that were discussed with Kable Bo Davis on 12/3/15:

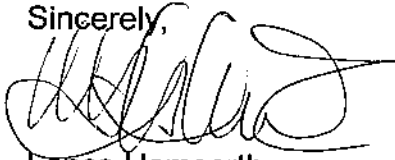
- Net Contents - the addition of a single tube package and a 6 tube package.
- The text after Net Contents would read , (For use) ONLY (for use) on cats (& kittens) 8 weeks and older, weighing 3 lbs. or more.

Included with this application are:

- Completed application form 8570-1;
- 3 copies of the Master Label. Additions are highlighted.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 2269 email me at lhemsarth@hartz.com

Sincerely,

A handwritten signature in black ink, appearing to read 'Lance Hemsarth', with a stylized, cursive script.

Lance Hemsarth
Senior Director, Research & Development

Encl.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
2596-179

2. EPA Product Manager
Kable Bo Davis

3. Proposed Classification
☒ None ☐ Restricted

4. Company/Product (Name)
Hartz Reference #144

PM#
3

5. Name and Address of Applicant (Include ZIP Code)

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to
Agency letter dated _____
"Me Too" Application.

☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Submission R315; New product registration application. Previously filed under File symbol 2596-RTL. MRIDs from data filed with that action cited herein.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☒ Yes
☐ No

Unit Packaging

☒ Yes
☐ No

Water Soluble Packaging

☐ Yes
☒ No

2. Type of Container

☐ Metal
☒ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

*** Certification must
be submitted**

If "Yes"
Unit Packaging wgt.
Varies

No. per
container
see label

If "Yes"
Package wgt

No. per
container

3. Location of Net Contents Information

☒ Label ☐ Container

4. Size(s) Retail Container

see label

5. Location of Label Directions

☒ On label

6. Manner in Which Label is Affixed to Product

Printed

☐ Lithograph
☒ Paper glued
☐ Stenciled

☐ Other on doses

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

Lance Hemsarh

Title

Senior Director R&D

Telephone No. (Include Area Code)

201-271-48CC, ext 2269

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or
both under applicable law.

2. Signature

3. Title

Senior Director R&D

4. Typed Name

Lance Hemsarh

5. Date

12/4/15

6. Date Application
Received

(Stamped)

PROCESSING REQUEST

Reg # 2596-179

Decision # 508889

Description: revised basic csf

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: revised basic CSF dated 08/25/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Kable Bo Davis

Division: RD

Phone: 306-0415

Date: 10/01/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 1, 2015

Lance Hemsarh
Sr. Director, R&D
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094-3688

Subject: CSF Amendment – Revised Basic CSF
Product Name: Hartz Reference #144
EPA Registration Number: 2596-179
Application Date: 09/01/2015
Decision Number: 508889

Dear Mr. Hemsarh:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 08/25/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Kable Bo Davis by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, loopy oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Davis, Kable

From: rosenwasser@verizon.net
Sent: Thursday, October 01, 2015 2:22 PM
To: Davis, Kable
Cc: Lance Hemsarh
Subject: Re: New Formulator's Exemption Statement
Attachments: 2596-179.pdf

resubmission

Mr. Davis:
Please find the corrected form.
Sincerely,
Robert Rosenwasser

From: Davis, Kable
Sent: Thursday, October 01, 2015 2:12 PM
To: rosenwasser@verizon.net
Cc: Lance Hemsarh
Subject: RE: New Formulator's Exemption Statement

Hi Robert –

Thanks for sending, however you have the wrong CSF date on the Formulator's Exemption. Would you please revise it to read "08/25/2015" and then resend? I have my signed letter ready to go.

Thanks,
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: rosenwasser@verizon.net [mailto:rosenwasser@verizon.net]
Sent: Thursday, October 01, 2015 1:54 PM
To: Davis, Kable
Cc: Lance Hemsarh
Subject: New Formulator's Exemption Statement
Importance: High

Dear Mr. Davis:
Please find attached a new Formulator's Exemption Statement for EPA Reg. No. 2596-179. The CSF for this amendment has been previously submitted. If you have any questions or need additional information, please contact me at 215-715-6419.
Sincerely,
Robert Rosenwasser
The Hartz Mountain Corporation



September 1, 2015

Document Processing Desk (AMEND)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis, PM-3

**Amendment to change source of approved active ingredient in Basic Confidential Statement of Formula of Hartz Reference 144, EPA Reg. No. 2596-179.
PRIA Action R340**

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is filing this amendment to change the source of the approved active ingredient (fipronil) in the Basic Confidential Statement of Formula of Hartz Reference 144, EPA Reg. No. 2596-179.

Hartz is seeking this measure to change our fipronil source of supply. We have sought other remedies but the Agency has disallowed our efforts to add an additional source of an EPA approved active ingredient to the formulation. We had argued that the active ingredient change would have no impact on the safety or performance of the product.

However, Hartz now realizes that the provision in the Pet Advisory which states that all topical products must have only one Basic Confidential Statement of Formula, creates a barrier to change, especially a significant one as in sourcing a different active ingredient supplier.

In order for Hartz to change our active ingredient supplier, we are filing this amendment to substitute a new source of active ingredient onto our Basic Confidential Statement of Formula. As both actives (our current and proposed) are substantially similar and well characterized by EPA, a change of one to the other poses no anticipated changes in the safety and efficacy of the product.

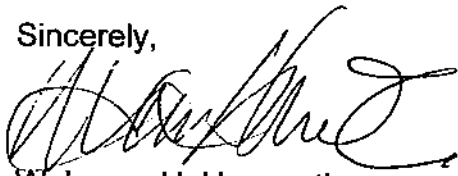
Additionally, Hartz would gain a new source of supply and at the same time conform to the Pet Advisory's restriction to one Basic CSF per topical registration.

Included with this application are:

- Completed application form 8570-1;
- One copy of new Basic Confidential Statement of Formula, dated 8-25-2015;
- Copy of Data Matrix and;
- Copy of fee letter to St. Louis.

If you have any additional questions or need any information, please feel free to contact me at 201-271-4800, ext. 2269 or email me at lhemsarth@hartz.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Lance H. Hemsarth', written in a cursive style.

W. Lance H. Hemsarth
Senior Director, Research and Development



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-179	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference 144	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, New Jersey 07094-3688 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment is filed to change source of active ingredient supply on Basic Confidential Statement of Formula, PRIA Action Code R340

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Lance Hemsarh		Title Sr. Director, R&D	
		Telephone No. (Include Area Code) 201-271-4800 ext. 7562	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Sr. Director, R&D	
4. Typed Name Lance Hemsarh		5. Date September 1, 2015	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 1, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-508889
EPA File Symbol or Registration Number: 2596-179
Product Name: HARTZ REFERENCE # 144
EPA Receipt Date: 03-Sep-2015
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

LANCE HEMSARTH
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Recoding of Registration Amendment

Dear Registrant:

The Office of Pesticide Programs has recoded your amendment that now is not subject to a Pesticide Registration Service Fee. This action is now a fast-track amendment.

This action has been identified as action code 345:

FORMULA CHANGE;TECHNICAL;

Since there is no longer a fee due for this action, the payment via check number 342548 in the amount of \$3,798 can either be refunded to you (the refund process takes about 8 weeks) or it can be held in reserve for a future PRIA action. Please contact me at yanchulis.michael@epa.gov to let me know what you would like me to do concerning the payment.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m/zh".

Front End Processing Staff
Information Technology & Resources Management Division

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 9-24-15

Document Part Of: 2596 - 179
MRID, If Any: _____

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

STEPHEN SCHABLE

HARTZ

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

September 1, 2015

U.S. Environmental Protection Agency
Washington Finance Center
FIFRA Service Fees
P.O. Box 979074
St Louis, MO 63197-9000

RE: FIFRA Fee submission for Hartz Mountain Corporation
EPA Reg. No. 2596-179 (PRIA R340)

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 is submitting a check for \$3,798.00 for the registration amendment application fee for Hartz Reference 144, EPA Reg. No. 2596-179. The PRIA Action Code is R340.

If you have any questions or need additional information, please contact me at 201-271-4800, ext. 7415 or email me at imatias@hartz.com.

Ida Matias



Regulatory Affairs



Hartz®


THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

No. **342548**

DATE: 31-AUG-15

VENDOR NAME: US ENVIRONMENTAL PROTEC

VENDOR NO: 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
EPA REGIS PRIA-340	28-AUG-15	1000118830	0.00	3,798.00
<p style="text-align: center;">*  2596-179</p>				

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT.

Thank You!

0.00

3,798.00

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK (CON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK.)

Hartz®

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS NJ, 07094

Bank of America

64-1278
611 GA

No. **342548**

CHECK DATE
31-AUG-15

CHECK NUMBER
342548

CHECK AMOUNT
*****3,798.00

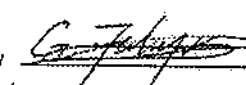

PAY Three Thousand Seven Hundred Ninety-Eight Dollars And 00 Cents****

TO
THE
ORDER
OF

US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE REGISTRATION SERVICE FEE
PO BOX 979031
ST LOUIS, MO 63197-9000

By

By

MADE IN U.S.A.

⑈ 342548 ⑈

Fee for Service

{973791C~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 3

Receipt No.

S- 973791

EPA File Symbol/Reg. No.

2596-179

Pin-Punch Date:

9/3/2015

This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3798.-

Parent/Child Decisions:

☒ ^{SV 9/8/15} Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: RD Date: 9/8/15

Remarks: Note: No CSF included in submission.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 8, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-508889
EPA File Symbol or Registration Number: 2596-179
Product Name: HARTZ REFERENCE # 144
EPA Receipt Date: 03-Sep-2015
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

LANCE HEMSARTH
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,


Patricia Owens
Front End Processing Staff

Information Technology & Resources Management Division

PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9/3/15

Experts In-Processing Signature: MP

Date 9/8/15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐

Date

EPA Reg. Number: <u>2596-179</u>		EPA Receipt Date: <u>9/3/15</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		<input checked="" type="checkbox"/>		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes <input checked="" type="checkbox"/> no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent		<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes <input type="checkbox"/> no			
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				<input checked="" type="checkbox"/>
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		<input checked="" type="checkbox"/>		
	a) Selective Method (Fee category experts use)	yes <input checked="" type="checkbox"/> no			
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			<input checked="" type="checkbox"/>	
7	Is the data package consistent with PR Notice 86-5				<input checked="" type="checkbox"/>
8	Notice of Filing included with petitions				<input checked="" type="checkbox"/>

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
<p>Comments:</p> <p>Documentation <u>Pass</u> or Fail</p> <ul style="list-style-type: none"> - Public Data Matrix Missing - Certification with respect to Citation - Data Missing - Submitter Contacted 9/9/15 - Forms Received - required forms are complete <p>Inerts <u>Pass</u> or Fail</p> <ul style="list-style-type: none"> - Inerts Approved for Non-Food Use <p>PRN II-03: <u>Pass</u> or Fail</p> <ul style="list-style-type: none"> - No Studies Submitted <p>Overall Status: <u>Pass</u> or Fail</p> <p>SV 9/10/15</p>				

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Varner, Stephanie

From: rrosenwasser@verizon.net
Sent: Thursday, September 10, 2015 11:23 AM
To: Varner, Stephanie
Cc: Ashe, Anthony
Subject: Fw: Submission to EPA: Hartz Reference 144 (EPA Reg. No. 2596-179)
Attachments: 2596-179 - Certification with Respect to Citation.pdf; 2596-179 Data Matrix.pdf

Stephanie:

On behalf of Lance Hemsarh, I am attaching the files that you have requested for EPA Reg. No. 2596-179. Please let me know if you need additional information.

Sincerely,

Robert Rosenwasser

From: LHemsarh@hartz.com
Sent: Wednesday, September 09, 2015 3:46 PM
To: rrosenwasser@verizon.net
Subject: Fw: Submission to EPA: Hartz Reference 144 (EPA Reg. No. 2596-179)

FYI and follow up please.

Thanks

W. Lance H. Hemsarh
Senior Director, R&D
lhemsarh@hartz.com
201-271-4800 x2269

----- Forwarded by Lance Hemsarh/ML1 on 09/09/2015 03:41 PM -----

From: "Varner, Stephanie" <Varner.Stephanie@epa.gov>
To: "lhemsarh@hartz.com" <lhemsarh@hartz.com>,
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>
Date: 09/09/2015 01:07 PM
Subject: Submission to EPA: Hartz Reference 144 (EPA Reg. No. 2596-179)

Dear Mr. Hemsarh,

My name is Stephanie Varner, and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the product Hartz Reference 144 (EPA Reg. No. 2596-179). We have found a few deficiencies with the submissions that will need to be addressed:

1. Please submit a Certification with Respect to Citation of Data (EPA Form 8570-34).
2. Please submit a Public Data Matrix.

Please send the necessary documents before Sep 24th so that we may further process your submission. After Sep 24th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Stephanie Varner

Contractor, US EPA
2777 S. Crystal Drive, S-4813
Arlington, VA 22202
(703) 347-0240
Email: varner.stephanie@epa.gov

LABORATORY TEST REPORT

Person Requesting Work: L. Needham

Dept: CPD

Work Request Number: 14580

NBR: 4075/2

Work Done by: S. Hatzikyriakou

Date: 3/10/14

PH of Fipronil 3X Drops

<u>Sample</u>	<u>PH (at 25degC)</u>
Drops for Dogs 4074-23	7.3
Drops for Cats 4074-24	7.4

